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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,052	02/26/2004	Chulwook Kim	3884-0119P	3294

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EXAMINER

GAMETT, DANIEL C

ART UNIT PAPER NUMBER

1647

DATE MAILED: 10/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/786,052	Applicant(s) KIM ET AL.	
	Examiner Daniel C. Gamett, PhD	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election with traverse of claim 5 in the reply filed on 08/11/2006 is acknowledged. Upon further consideration, the requirement for restriction/election is hereby withdrawn.

2. Claims 1-5 are under examination.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-5 are rejected under 35 U.S.C. 101 because the claimed inventions are directed to non-statutory subject matter. Each claim is drawn to a nucleotide sequence as set forth in a SEQ ID NO. Firstly, a "nucleotide sequence" is not a process, machine, manufacture, or composition of matter. For purposes of examination, the claims are construed as being directed to nucleic acid molecules or polynucleotides. Furthermore, although each sequence is recited to be "derived from *Kagoshima Berkshire*", this indicates a species of origin but does not clearly indicate isolation or purification of the claimed polynucleotides. By failing to specify any human input or activity, the claims read on polynucleotides as they exist in nature. Products of nature do not constitute patentable subject matter. This rejection may be obviated by recitation of an *isolated* polynucleotide comprising the sequence set forth in SEQ ID NO:1, for example.

5. Claims 1-5 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility. Each claim is drawn to a polynucleotide having the nucleotide sequence as set forth in one of SEQ ID

Art Unit: 1647

NOs: 1-5. The specification asserts, in the abstract, that, “the growth-related genes derived from pig according to the present invention can be used in feeds for increasing the daily body weight gain of pig or applied in genetic improvement of pig with excellent growth performance. Thus, the present invention is very useful for the hog raising industry.” However, there is no teaching in the specification, nor any indication in the prior art, as to how the claimed gene sequences can be specifically useful or informative with regard to swine improvement. Firstly, “used in feeds” is not a specific utility. Any protein or nucleic acid can have nutritional value. Furthermore, as the instant claims are drawn to nucleic acid molecules, the “used in feeds” utility must envision feeding nucleic acids for the purpose of “increasing the daily body weight gain of pig”. The specification does not provide even a theoretical basis for believing that the use of the claimed nucleic acids as feeds would have any effect other than the basic nutritional value that might be provided by any nucleic acid. As for “applied in genetic improvement”, this asserted utility appears to extend from the assertion that the claimed genes are “growth-related”. The specification, however, does not establish any specific relationship of the claimed genes and growth. The genes were identified merely on the basis of their expression in muscle and fat tissues of adult pigs [0008; 0011; 0018]. [NB-- Citations of the specification refer to U.S Patent Application Publication 20050113568.] Therefore, the specification does not show that any gene is “growth-related”; at best, the expression of the claimed genes may be muscle or fat specific. For SEQ ID NOs: 1-4, even tissue-specific expression is doubtful in view of the prior art. SEQ ID NO:1 is identical to a mouse gene expressed in a mammary tumor (GenBank Locus BC004067); SEQ ID NO: 2 is identical to swine myosin heavy chain 2b (e.g. GenBank Locus AB025261); SEQ ID NO: 3 shows highest similarity to human cDNAs variously described as

Art Unit: 1647

“cancer-related” or “transactivated by hepatitis C virus NS3 protein” (e.g. GenBank Loci BD079915 and AY116969); SEQ ID NO: 4 shows highest similarity to a human alpha-actin mRNA (e.g. GenBank Locus HUMACTASK) [Sequence search results and alignments are available in SCORE; see the “Supplemental Content” tab under “Image File Wrapper” in PAIR]. Furthermore, even if the collective and simultaneous expression of the genes of SEQ ID NOs:1-5, as measured by microarray technology for example, were to be found to be indicative of growth, there is no basis for asserting that any individual sequence has the same correlation. The asserted utilities, therefore, do not constitute a substantial utility for the claimed invention, since further experimentation would be required to establish a real world use for the claimed invention.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-5 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by GenBank Accession No. BC004067. Version BC004067.1, which was available at NCBI on March 12, 2001, is 100% identical to SEQ ID NO:1 over the entire length [Search results are available in SCORE; see Alignment in Item ID 637250 in Public PAIR]. Insofar as “derived from *Kagoshima Berkshire*” may indicate a process of making the claimed product, the courts have established that if a claimed product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983).

10. Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by GenBank Accession No. AB025261. Version AB025261.1, which was available at NCBI on July 6, 1999 is 100% identical to SEQ ID NO:2 over the entire length [Search results are available in SCORE; see Alignment in Item ID 637256 in Public PAIR]. Insofar as “derived from *Kagoshima Berkshire*” may indicate a process of making the claimed product, the courts have established that if a claimed product in a product-by-process claim is the same as or obvious from a product of the

Art Unit: 1647

prior art, the claim is unpatentable even though the prior art product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983).

Conclusion

11. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C Gamett, Ph.D., whose telephone number is 571 272 1853. The examiner can normally be reached on M-F, 8:30-5:00.

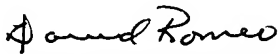
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571 272 0961. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DCG

Art Unit 1647

11 October 2006


DAVID S. ROMEO
PRIMARY EXAMINER